

*044.P001*Patent**REMARKS**

The above-referenced patent application has been reviewed in light of the Office Action and the Notice of Non-Compliant Amendment referenced above. Please enter the following amendments and consider the following remarks.

Reconsideration of the above-referenced patent application in view of the following remarks is respectfully requested.

Claims 1-18 are pending in the application. Claims 1-5, 6-8, and 10-18 have amended and claims 5 and 9 have been cancelled without prejudice. The amendment is fully supported by the disclosure filed on October 7, 2005. No new matter has been introduced.

Informalities

Applicant notes that the Examiner crossed out reference FR 2787730A, dated 6/30/2000, which applicant included in an IDS filed on August 14, 2007. Apparently, the Examiner did not consider this reference in the last Office Action mailed March 6, 2008.

Objection to the Title

The Examiner has objected to the title and required a new title due to the term "novel".

Accordingly, Applicant has amended the title to remove the term "novel". Applicant respectfully submits that the title is now in proper form.

Claim objections

Claims 5-18 have been objected to for being in improper multiple dependent form.

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Applicant has cancelled claims 5 and 9 and amended claims 6-8 and 10-18: None of the amended claims comprise multiple dependent form. Accordingly, Applicant respectfully submits that this objection is moot in view of the claim amendments.

Claim rejections – 35 USC §112

Claim 1 is rejected under 35 U.S.C. 112 for indefiniteness for use of the term "such as".

Accordingly, Applicant has amended the title to remove the term "such as".

Accordingly, Applicant respectfully submits that this objection is moot in view of the claim amendments.

Claim rejections – 35 USC §102

Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Shalaby et al. (U.S. Patent No. 4,186,189).

Applicant respectfully submits the Examiner has not established that the cited references disclose all of the elements of independent claim 1. The Examiner is kindly reminded that the Examiner's initial burden of factually supporting any *prima facie* case of anticipation requires that the prior art reference must teach every element or limitation of a claim. See MPEP § 2131. For example, Examiner has not established that Shalaby discloses:

... a pharmaceutical composition comprising poly(ethylene sebacate);

as recited in amended claim 1. At page 4 of the present Office Action, the Examiner has characterized Shalaby as follows:

... Shalaby et al. teach a pharmaceutical composition with one or more drugs and the absorbable (biodegradable), aliphatic polyester, poly(alkylene oxalate)...

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However, Applicant respectfully submits that the Examiner has not addressed "*a pharmaceutical composition comprising poly(ethylene sebacate)*" as recited in amended claim 1. For at least this reason, Applicant respectfully submits that amended independent claim 1 and dependent claims 2-4, 6-8, and 10-18 are not anticipated or rendered obvious by the cited document. Thus, Applicant respectfully requests that the rejection be withdrawn.

Claim rejections – 35 USC §103

To successfully make a *prima facie* rejection under 35 USC § 103, the Examiner must show that Applicant's claimed subject matter would have been obvious to one of ordinary skill in the art pertinent to Applicant's claimed subject matter at the time it was made. See KSR International, Co. v. Teleflex, Inc., 127 S.Ct. 1727 (decided April 30, 2007). Some of the factors to consider in this analysis include the differences between the applied documents and Applicant's claimed subject matter, along with the level of skill associated with one of ordinary skill in the art pertinent to Applicant's claimed subject matter at the time it was made. One way in which an Examiner may establish a *prima facie* case of unpatentability under 35 USC § 103 would be to show that three basic criteria have been met. The Examiner, therefore, first, should show that the applied document(s), alone or in combination, disclose or suggest every element of Applicant's claimed subject matter. Second, the Examiner should show that there is a reasonable expectation of success. Finally, the Examiner should show that there was some suggestion or motivation, either in the applied document(s) themselves or in the knowledge generally available to one of ordinary skill in the art, to, in this case, modify or combine the applied document(s). The motivation or suggestion and the reasonable expectation of success should be found in the prior art, and should not be based on Applicant's disclosure. See In re Vaeck, 947 F.2d 488, 20

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USPQ2d 1438 (Fed. Cir. 1991); See MPEP § 2142; 2143 - § 2143.03 (regarding decisions pertinent to each of these criteria). It is respectfully asserted that the Examiner has not met this standard.

Furthermore, on October 10, 2007, the USPTO published in the Federal Register its Examination Guidelines under 35 USC § 103 in view of the KSR decision, cited above. These guidelines contain a number of relevant points. In particular, the new Guidelines state that an Examiner must articulate a reason or rationale to support an obviousness rejection. Specifically, Examiner's must articulate findings as to the scope and content of the prior art to support the obviousness rejection being made. The Examiner should focus on the state of the art and not on impermissible hindsight (e.g., from inappropriate use of Applicant's disclosure). Specifically, Examiners need to account for all claim limitations in the rejections, either by indicating where each limitation is shown by the applied documents or by providing an explanation of how the document is relevant to an obviousness determination despite the limitation not being shown. Thus, Examiners must explain reasoning that provides a nexus between the factual findings and the legal conclusions of obviousness. It is respectfully asserted that the Examiner also has not met these standards.

As discussed above, the applied documents do not provide, inherently or otherwise, all of the elements of the pending claims. Furthermore, the documents applied by the Examiner do not cure this deficiency. For at least these reasons, Applicant respectfully asserts that the Examiner's rejection of the claims is improper.

Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalaby et al.

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Applicant respectfully submits that, for at least the reasons presented above with respect to the rejection of claim 1 under 35 U.S.C. 102, Shalaby fails to teach or suggest all the claim limitations of claim 1. Accordingly, Applicant respectfully submits that claim 1 is not rendered obvious in view of Shalaby and, for at least this reason, respectfully requests withdrawal of the rejection of claim 1 under 35 U.S.C. 103(a).

Claims 3-4, 6-8, and 10-18 are similarly not obvious, at least on the same or similar basis as claim 1. Thus, Applicant respectfully requests withdrawal of this rejection.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penhasi (U.S. Publication No. 2003/0208259) in view of Farachi et al. (U.S. Patent No. 6,562,939) and Zhu et al. (Chinese Chemical Letters 2001 12(7):589-592).

Assignee respectfully submits the Examiner has not established that the documents disclose all of the elements of independent claim 1. For example, Examiner has not established that the proposed combination discloses:

... wherein said pharmaceutical composition is in the form of different drug delivery systems, wherein said drug delivery systems comprise one or more of the following structures: drug loaded microparticles, microcapsules, nanoparticles, molded implants, coated granules, films, coated tablets, ophthalmic inserts, fibers, ligatures or sutures.

as recited in amended claim 1. At page 6 of the present Office Action, the Examiner points to Penhasi as disclosing use of a stent, stating:

Penhasi teaches a stent with a polymer and drug (see paragraph 22-24; instant claim 1). Specifically Penhasi teaches the drug being incorporated in a polymer matrix where, polyethylene sebacate is taught as one of the preferred polymers (paragraph 35 line 33-34; instant claims 1 and 2).

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However, Applicant respectfully submits that the Examiner has not established that the stent of Penhasi shows “*drug delivery systems*” as recited in amended claim 1. More specifically, the Examiner has not established that the stent of Penhasi shows “*drug loaded microparticles, nanoparticles, molded implants, coated granules, films, coated tablets, ophthalmic inserts, fibers, ligatures or sutures*” as recited in amended claim 1. Additionally, Applicant respectfully submits that the Examiner has not established that Farachi and/or Zhu cure Penhasi of this deficiency. In the absence of the Examiner pointing to such a disclosure in the documents, Assignee requests that the rejection be withdrawn as the Examiner failed to establish that the documents render obvious claim 1.

Claim 2 is similarly not obvious, at least on the same or similar basis as claim 1. Thus, Applicant respectfully requests withdrawal of this rejection.

It is noted that claimed subject matter may be patentably distinguished from the cited documents for additional reasons; however, the foregoing is believed to be sufficient. Likewise, it is noted that the Applicant’s failure to comment directly upon any of the positions asserted by the Examiner in the office action does not indicate agreement or acquiescence with those asserted positions.

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Patent**Conclusion**

In light of the foregoing, reconsideration and allowance of the claims is hereby earnestly requested.

Any fees or extensions of time believed to be due in connection with this amendment are enclosed herein; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account 50-3130.

Invitation for a Telephone Interview

The Examiner is invited to call the undersigned attorney, Brian D. Wichner, at (503) 439-6500 if there remains any issue with allowance.

Respectfully submitted,
Attorney for Applicant

Dated: May 6, 2009/Brian D. Wichner/Brian D. Wichner
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